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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

FEDERAL TRADE COMMISSION,  
Plaintiff,

v.

LANE LABS-USA, INC., CARTILAGE  
CONSULTANTS, INC., corporations, and  
I. WILLIAM LANE and ANDREW J. LANE,  
individuals,

Defendants.

Hon. Dennis M. Cavanaugh

00CV3174 (DMC)

**MEMORANDUM OF PLAINTIFF  
FEDERAL TRADE COMMISSION IN  
SUPPORT OF MOTION FOR ORDER TO  
SHOW CAUSE WHY DEFENDANTS  
SHOULD NOT BE HELD IN CONTEMPT**

**RETURN DATE: FEBRUARY 12, 2007**

## Table of Contents

Table of Authorities .....	iii
I. Procedural History and Injunctions .....	3
II. The Products and Claims at Issue .....	4
A. Fertil Male .....	4
B. AdvaCAL .....	6
III. Legal Argument .....	10
A. Defendants are Liable for Civil Contempt .....	10
1. Defendants are Bound by Valid Court Orders of Which They had Knowledge .....	12
2. The Defendants Disobeyed the Orders .....	12
a. The Defendants Have Violated the Order Against Lane Labs by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claim that Fertil Male Improves Fertility, and by Misrepresenting the Results of Studies of this Product .....	12
b. The Defendants Have Violated the Orders by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claims Regarding AdvaCAL, and by Misrepresenting the Results of Scientific Research .....	18
i. The Evidence Does Not Substantiate the Defendants' Claim that AdvaCAL is More Absorbable Than Other Types of Calcium .....	20

ii.	The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium or Prescription Products at Building Bone or Increasing Bone Mineral Density .....	23
iii.	The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium Products in Avoiding or Reducing the Risk of Fractures .....	30
B.	William Lane is in Contempt of the Order Against Him Because he Made Unsubstantiated Representations as an Expert Endorser for AdvaCAL .....	33
C.	Consumers Must be Compensated for the Defendants' Contumacious Behavior .....	35
IV.	Conclusion .....	36

Table of Authorities

Cases

Ardex Laboratories, Inc. v. Cooperider  
319 F.Supp.2d 507 (E.D. Pa. 2004) ..... 11

Al C. Rinaldi, Inc. v. Bach to Rock Music School, Inc.  
279 F.Supp.2d 624 (E.D. Pa. 2003) ..... 11

FTC v. Affordable Media, LLC  
179 F.3d 1228 (9<sup>th</sup> Cir. 1999) ..... 11

Gunn v. University Committee to End the War in Viet Nam  
399 U.S. 383 (1970) ..... 10

Harris v. City of Philadelphia  
47 F.3d 1342 (3d Cir. 1995) ..... 11

In re Affairs with a Flair  
123 B.R. 724 (Bankr. E.D. Pa. 1991) ..... 11

John T. v. Delaware County Intermediate Unit  
318 F.3d 545 (3d Cir. 2003) ..... 11

Lawson v. FTC  
534 U.S. 1042 (2001) ..... 11

McDonald’s Corp. v. Victory Investments  
727 F.2d 82 (3d Cir. 1984) ..... 11

Metagenics  
1996 WL 615822 at \*19 (F.T.C. October 11, 1996) ..... 19

Robin Woods Inc. v. Woods  
28 F.3d 396 (3d Cir. 1994) ..... 11

Roe v. Operation Rescue  
54 F.3d 133 (3d Cir. 1995) ..... 11

Shillitani v. United States  
384 U.S. 364 (1966) ..... 10

U.S. v. Lane Labs-USA  
2005 U.S. App. LEXIS 22734 ..... 3-4

In 2000, the Federal Trade Commission (“FTC”) entered into Stipulated Final Orders<sup>1</sup> with the Defendants in connection with their marketing and sale of two products: SkinAnswer and BeneFin. Each order required the Defendants to have competent and reliable scientific evidence to substantiate any representation they made regarding the effect of any product on any disease or disorder or the structure or function of the human body, or about any other health benefits of such product. (Tabs A and B ¶ III.) The orders also barred the Defendants from misrepresenting the results of any tests, studies or research. (Tabs A and B ¶ IV.) The FTC is now compelled, once again, to take action against the Defendants based on spurious and contemptuous claims made in their advertising of two other products, Fertil Male and AdvaCAL. Accordingly, the FTC brings this Motion for Order to Show Cause Why Defendants Should not be Held in Contempt.

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<sup>1</sup> On June 30, 2000, the parties jointly submitted two Stipulated Final Orders to this Court (Bassler, J.), one pertaining to Lane Labs-USA, Inc. (“Lane Labs”) and Andrew Lane, and the other pertaining to Cartilage Consultants, Inc. and I. William Lane (“William Lane”). On July 6, 2000, this Court (Bassler, J.), entered the Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to the latter Defendants only. After resubmission by the parties on September 26, 2000, this Court, on September 28, 2000, entered the Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief as to Lane Labs and Andrew Lane.

Since at least 2003, Defendants Lane Labs and Andrew Lane<sup>2</sup> have been marketing and selling Fertil Male. Lane Labs has expressly and impliedly represented through its labeling and advertising that this product improves male fertility. It has done so, however, based on irrelevant and flawed scientific studies, and accordingly, has failed to substantiate its claims. Lane Labs' claims about the efficacy of Fertil Male likewise distort and misrepresent the results of tests and studies on this product, in violation of the Order.

Defendants Lane Labs and Andrew Lane have marketed and sold AdvaCAL since 2000. Lane Labs also makes numerous unsubstantiated claims about the benefits of this calcium product and, in doing so, has misrepresented the results and conclusions of tests and studies. The conclusions of these studies do not support the Defendants' claims, and, in any event, the studies themselves are fatally flawed. William Lane has been complicit in making these claims – actively promoting this product through appearances as an expert endorser in print advertisements and infomercials – and accordingly, has violated the Order separately entered against him.

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<sup>2</sup> Andrew Lane, President and sole shareholder of Lane Labs, is actively involved in the advertising and marketing of Lane Labs' products.

The Defendants' unsubstantiated claims constitute contempt and have resulted in injury to consumers. Compensation to these consumers is necessary in order to remedy the Defendants' contempt. Therefore, the FTC asks that this Court grant its Motion for Order to Show Cause Why Defendants Should not be Held in Contempt, and other appropriate relief.

## **I. Procedural History and Injunctions**

On June 27, 2000, the FTC filed an action in this Court against Cartilage Consultants, Inc., William Lane, Lane Labs and Andrew Lane. The FTC's allegations against these Defendants involved two products marketed and sold by Defendants: BeneFin and SkinAnswer. The FTC charged the Defendants with making unsubstantiated claims about the efficacy of these products in treating cancer; false representations regarding the clinical proof of the efficacy of these products; and false representations regarding the Food and Drug Administration's evaluation of BeneFin.<sup>3</sup> The FTC's prayer for relief sought an injunction against

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<sup>3</sup> In December 1999, the Food and Drug Administration sued Lane Labs for promoting BeneFin (shark cartilage), Skin Answer (skin cream), and another product, MGN-3 (rice bran/shiitake mushroom), as drugs without requisite new drug FDA approval. In July 2004, the district court issued a permanent injunction against future sales of the products "or any drug that is a 'new drug' until a new drug application was approved for them," and ordered restitution. Lane Labs appealed the District Court's authority to grant restitution under the Federal Food, Drug and Cosmetic Act. On October 21, 2005, the Third Circuit affirmed the district court's order of restitution. U.S. v. Lane Labs-USA, 2005

unsubstantiated claims for the two products, misrepresentation of test results; refund of monies paid by purchasers of the products, and disgorgement. The Defendants settled these claims, and settlement led to the entry of the Orders referenced above. The Defendants have acknowledged receipt of the Orders. (Tab C Exhs. 1 and 2.)<sup>4</sup>

## **II. The Products and Claims at Issue**

### **A. Fertil Male**

Since 2003, Lane Labs has marketed Fertil Male as a “natural supplement for male fertility.” The product contains LMG, a Peruvian plant root also known as maca or *Lepidium meyenii*. (Tab C ¶ 39.) A one-month supply of Fertil Male costs \$39.95 at retail. (Tab C Exh. 28.)

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U.S. App. LEXIS 22734. Lane Labs subsequently settled this matter for \$8 million.

<sup>4</sup> Under the Orders, the Defendants were, within sixty (60) days after entry of the Orders, and “at such other times as the Commission [might] reasonably require,” to file reports with the Commission demonstrating their compliance with the Order. At the FTC’s request, the Defendants submitted compliance reports in 2001, 2004, and 2006. (Tab C ¶ 2.) Included in the 2001, 2004 and 2006 reports, among other things, were copies of Lane Labs’ advertising for AdvaCAL. Included in the 2004 and 2006 compliance reports were copies of Lane Labs’ advertising for Fertil Male. (Tab C ¶ 2.) Also included in these compliance reports were studies and other research on which the Defendants rely in support of their claims for these products. (Tab C ¶ 2.)

Advertising and promotional claims for Fertil Male appear in four sources: (1) the product label; (2) CompassioNet catalogs from 2003-2006; (3) the current CompassioNet website; and (4) the current Lane Labs website. (Tab C ¶ 3 Exhs. 26-31.)

The Defendants, on the label for the product, state that “Fertil Male is clinically shown to promote sperm count and motility.” (Tab C Exh. 27.)

Lane Labs and/or CompassioNet websites and CompassioNet catalogs are replete with bold claims that Fertil Male will enhance a man’s fertility. For example:<sup>5</sup>

“Fertil Male is clinically shown to promote sperm count, sperm motility (movement) and semen production without changing hormone levels. It has LMG, a Peruvian plant root infused with HAI, a patented amino acid complex that dramatically enhances absorption. In one human research study, benefits were noted in four months.” (Tab C Exh. 27.)

[Testimonial] “LMG is an important ingredient that helps promote male fertility. Most of its attributed properties have been corroborated scientifically.” (Tab C Exh. 27.)

“HUSBAND + WIFE + FERTIL MALE = ONE BIG HAPPY FAMILY!  
Kelli and Joe Faber ... love being parents. It took them 2 years and a lot of trying to have Cassandra (now 4). So when they started thinking about having another baby, Kelli suggested something different. A Lane Labs employee, Kelli had read the research on Fertil Male. ... Kelli brought some home for Joe to try. The results were dramatic. In the first month, Joe’s sperm count skyrocketed. And less than a year later, baby Madeline made

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<sup>5</sup> See also Tab C Exhs. 28 and 29.

her appearance. ‘We didn’t do anything special,’ Kelli marvels. ‘It just happened.’” (Tab C Exhs. 30 and 32.)

As the discussion below demonstrates, Lane Labs’ explicit and implicit claims that Fertil Male boosts fertility are unsubstantiated by competent and reliable scientific evidence, and misrepresent the results of tests and studies involving *Lepidium meyenii*.

## **B. AdvaCAL**

AdvaCAL, or AAACa, is an oyster-shell derivative. The shells (calcium carbonate) are super-heated, yielding calcium hydroxide and calcium oxide. This product is then combined with specially processed algae (“heated algae ingredient” or “HAI”), which Defendants claim enhances the absorbability of the calcium.

Lane Labs began marketing AdvaCAL in 2000. It advertises this product on its websites ([www.lanelabs.com](http://www.lanelabs.com) and [www.compassionet.com](http://www.compassionet.com)), the CompassioNet catalog, by direct mail, and on infomercials. (Tab C ¶ 3, 7, 19 Exhs. 1, 4-7, 8, 10-13.) During the period at issue in this case (2000 through the present), a 25 day supply of AdvaCAL (150 pills)<sup>6</sup> sold for \$39.95 at retail, which is many times the price of comparable calcium products. (Tab C ¶ 8 Exh.10.) As the discussion

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<sup>6</sup> Daily dose of 900 mg, 90% daily value.

below shows, Defendants have charged a premium for AdvaCAL based on unsupported and likely false representations of superiority.

Lane Labs' claims can be divided broadly into three categories. First, Lane Labs claims that AdvaCAL can "build bone" or increase bone mineral density where and to an extent other calcium and prescription products cannot. (Tab C Exhs. 4-13.) Second, Lane Labs claims that AdvaCAL reduces or prevents fractures, and that it reduced fractures among the elderly 100% over a three-year period. (Tab C Exhs. 10, 11, 14, 16.) Third, Lane Labs' advertisements claim that AdvaCAL is more absorbable, or in many cases, three times more absorbable, than other types of calcium. (Tab C Exhs. 8, 13-14, 17.)

The Defendants' "bone building" claim is made repeatedly in advertisements. (Tab C Exhs. 4-13.) The message repeated over and over by Lane Labs is that AdvaCAL is the "only" calcium product that can "build bone." (Tab C Exhs. 7, 12-13.)

Lane Labs also includes a chart in numerous advertisements (which, at least for some period, featured William Lane) touting AdvaCAL's supposed superiority over other calcium products. (Tab C Exhs. 10 and 11.) According to this chart, for post-menopausal women, AdvaCAL is nearly 4 times better than Calcium

Citrate Malate and nearly 3 times better than Calcium Citrate at building bone density.<sup>7</sup>

Defendants' deceptive superiority claims for elderly women are of a similar magnitude. Defendants claim that for an elderly population, AdvaCAL performs nearly 4 times better than Calcium Carbonate and approximately 1.6 times better than Calcium Hydroxy Apatite at improving bone density.<sup>8</sup>

Infomercials for AdvaCAL are replete with testimonials trumpeting the remarkable changes in bone density attributed to taking AdvaCAL. For example, a 28 year old reports a 20% increase in her bone density (Tab C Exh. 13); a 25 year old claims that her bone density increased by 50% after she took AdvaCAL (Tab C Exh. 13); a 39 year old claims that in one year her bone density went from 3% below average for her age to 20% above average (Tab C Exh. 12-13).

In addition to comparing AdvaCAL's supposed effectiveness in building bone to other calcium products' bone building effectiveness, Lane Labs has

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<sup>7</sup> On this chart, AdvaCAL shows a 2.6% increase in bone density over 2 years, compared to Calcium Citrate (approximately 1% over 2 years) and Calcium Citrate Malate (approximately -1.2% over 2 years). (Tab C Exhs. 10 and 11.)

<sup>8</sup> For this population, the Defendants claim that AdvaCAL increased bone density by approximately 3.1% over 2 years compared with Calcium Carbonate (approximately .8% over 2 years) and Calcium Hydroxy Apatite (approximately 1.9% over 2 years). (Tab C Exhs. 10 and 11.)

promoted the use of AdvaCAL in lieu of prescription treatments for osteoporosis. Through its website, Lane Labs provided a link for consumers to a newsletter published by the Health Sciences Institute (“The Battle for Your Bones”). (Tab C ¶ 12 Exh. 8). This newsletter contains a chart purporting to show that AdvaCal’s bone-building abilities are comparable or superior to Fosomax and Evista, two prescription products. (Tab C Exh. 8.) This chart purports to show that over a 2 year period, the change in spinal bone density was 3.2% for AdvaCAL, compared to 2% for Evista and 3.5% for Fosomax. (Tab C Exh. 8.) The article claims that “AAACa works as well or better than these expensive drugs, and without the substantial side effects and risks.” (Tab C Exh. 8.)

Lane Labs’ AdvaCAL advertisements also claim that it has fracture-reducing benefits. One chart referred to above indicates that there is a 100% fracture reduction for elderly patients over a 3 year period. (Tab C Exh. 10-11.) Other advertisements state that there were 0 fractures per 1000 patient years for AdvaCAL users compared with 357 for Calcium Carbonate users. (Tab C Exh. 14, 16.) A more general claim is made in an infomercial for AdvaCAL: “You don’t need to be in a nursing home because you broke your hip – all you have to do is take your AdvaCAL to prevent that.” (Tab C Exh. 13.)

Several of Lane Labs' advertisements focus on AdvaCAL's absorbability relative to other calcium products. These ads claim that AdvaCAL has been "clinically shown to be 3 times more absorbable than other calcium." (Tab C Exhs. 8.) This claim is repeated by William Lane and others in AdvaCAL infomercials.

There is no competent and reliable scientific evidence to support any of the above claims regarding AdvaCAL; and the Defendants' representations to the contrary misrepresent the tests and studies that pertain to AdvaCAL and the products to which Lane Labs claims it is superior. Therefore, under the terms of the Orders, a finding of contempt is warranted.

### **III. Legal Argument**

#### **A. Defendants are Liable for Civil Contempt**

The basic legal tenets governing civil contempt proceedings are well established under Supreme Court and Third Circuit authority. Courts possess the inherent authority to enforce compliance with their orders through civil contempt. Gunn v. University Committee to End the War in Viet Nam, 399 U.S. 383, 389 (1970); Shillitani v. United States, 384 U.S. 364, 370 (1966). "Civil contempt may be employed to coerce the defendant into compliance with the court's order and to compensate for losses sustained by the [defendant's] disobedience."

McDonald's Corp. v. Victory Investments, 727 F.2d 82, 87 (3d Cir. 1984).

The party seeking a finding of civil contempt must prove it by “clear and convincing evidence.” Id. See Roe v. Operation Rescue, 54 F.3d 133, 137 (3d Cir. 1995); Ardex Laboratories, Inc. v. Cooperider, 319 F.Supp.2d 507 (E.D. Pa. 2004); Al C. Rinaldi, Inc. v. Bach to Rock Music School, Inc. 279 F.Supp.2d 624, 627-28 (E.D. Pa. 2003). In order for a party to be held in civil contempt, a plaintiff must show that “(1) a valid court order existed, (2) the defendant had knowledge of the order, and (3) the defendant disobeyed the order.” John T. v. Delaware County Intermediate Unit, 318 F.3d 545, 552 (3d Cir. 2003) (quoting Harris v. City of Philadelphia, 47 F.3d 1342, 1326 (3d Cir. 1995)). The burden then shifts to the alleged contemnors to show why they were unable to comply with the order. FTC v. Affordable Media, LLC, 179 F.3d 1228, 1239 (9<sup>th</sup> Cir. 1999), cert. denied sub nom Lawson v. FTC, 534 U.S. 1042 (2001); In re Affairs with a Flair, 123 B.R. 724, 727 (Bankr. E.D. Pa. 1991).<sup>9</sup> As the discussion below demonstrates, the evidence that the Defendants were in contempt of the Orders against them is overwhelming.

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<sup>9</sup> Importantly, willfulness is not an element of contempt. Therefore, evidence of good faith does not bar the conclusion that a defendant acted in contempt. Robin Woods Inc. v. Woods, 28 F.3d 396, 399 (3d Cir. 1994).

**1. Defendants are Bound by Valid Court Orders of Which They had Knowledge**

The Defendants expressly stipulated to this Court’s final orders. They acknowledged receipt of the Orders (Tab C Exhs. 3 and 4), and have continued to do so through their multiple compliance submissions to the FTC. (Tab C ¶¶ 2-6.) As the president, chief executive officer and sole shareholder of Lane Labs, Defendant Andrew Lane has actual responsibility over the advertising, marketing, manufacturing, and distribution of Lane Labs’ products. (Tab C Exhs. 19, 21-26.) William Lane appeared in numerous Lane Labs advertisements for AdvaCAL and clearly participated in the marketing of the product. Thus, there is no question about whether each of the Defendants are individually subject to the Orders at issue and responsible for any violations of those Orders.

**2. The Defendants Disobeyed the Orders**

**a. The Defendants Have Violated the Order Against Lane Labs by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claim That Fertil Male Improves Fertility, and by Misrepresenting the Results of Studies of This Product**

As noted above, Lane Labs markets Fertil Male as a “natural supplement for male fertility,” and represents that Fertil Male has been “[c]linically shown to promote sperm count, sperm motility and semen production.” (Tab C Exh. 26 at

2.) Lane Labs makes both express and implied claims that Fertil Male boosts a man's fertility, as detailed in Section II.A.

Paragraph III of the Order against Lane Labs expressly bars the Defendants from making any

representation, in any manner ..., expressly or by implication, about the effect of [any] product on the structure or function of the human body, or about any other health benefits of such product, unless, at the time the representation is made, defendants possess and rely upon *competent and reliable scientific evidence* that substantiates the representation. (Emphasis added.)

(Tab A ¶ III.) Similarly, Paragraph IV of the Order bars the Defendants from misrepresenting “in any manner, expressly or by implication, ... the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.” (Tab A ¶ IV.)

Dr. Craig Niederberger, a urologist and male reproductive expert (Tab D ¶ 6), reviewed all of the data provided by the Defendants to substantiate their claims that *Lepidium Meyenii* (Maca roots),<sup>10</sup> Fertil Male's key ingredient, improved male fertility by increasing sperm count, motility, and production. (Tab D ¶¶ 6-12.)

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<sup>10</sup> Dr. Niederberger independently investigated whether there was other research on the effects of *Lepidium meyenii* on male fertility and found none. (Tab D ¶ 13.)

Dr. Niederberger concluded “that while *Lepidium meyenii* appears to function as a stimulatory agent for sexual behavior in animals and humans, [there is] no definitive, compelling, or analytically suggestive evidence that compounds based on [this substance] improve human male fertility.”<sup>11</sup> (Tab D ¶¶ 14.)

To reach his opinion, Dr. Niederberger looked both to animal and human studies. (Tab D ¶¶ 6-12.) As a general matter, he found that the animal studies on *Lepidium meyenii* focused on sexual behavior, not on the creation of sperm (Tab D ¶ 20), or male fertility. (Tab D ¶ 20.) Dr. Niederberger noted that “[w]here outcomes relating to *male fertility* were studied in animal models likely to simulate normal adult human male conditions, either statistically or clinically non-significant effects of *Lepidium meyenii* were reported.” (Emphasis added.) (Tab D ¶ 20.) Moreover, according to Dr. Niederberger, animal studies are insufficient, by themselves, to establish that *Lepidium meyenii* enhances human fertility. (Tab D ¶ 21.)

Dr. Niederberger likewise explained that the human studies on *Lepidium meyenii* are unconvincing and unreliable support for Defendants’ claim that this

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<sup>11</sup> Defendants’ own advertisements acknowledge the distinction between sexual behavior and fertility. See, e.g., Tab C Exh. 27 (“Sexual virility is the capability of having a pleasing sexual performance. This has nothing to do with the fertility status of a man. It is common for men to have perfectly normal sexual relations and have less than satisfactory fertility levels.”).

substance improves male fertility. (Tab D ¶¶ 21-22.) As with the animal studies, the human studies tended to address the effects of *Lepidium meyenii* on sexual behavior, rather than on male fertility. (Tab D ¶ 21.) Only two studies actually addressed human fertility. Dr. Niederberger identified two critical flaws with these studies: 1) the very small number of subjects (e.g., 12) (Tab D ¶¶ 21-23; and 2) the absence of a placebo group. (Tab D ¶¶ 21-22.)

Dr. Niederberger explains that the study by Dr. G.F. Gonzalez et al. (Tab D Exh. 2 at 8.2.1) consisted of only nine subjects (Tab D ¶ 21), a number far below the minimum number of subjects required in such a study. (Tab D ¶ 19.) Moreover, this study lacked any validity because it had no separate placebo group. (Tab D ¶ 21.) A placebo group is necessary to such a study “for a clear and critical reason.” (Tab D ¶ 18.) As Dr. Niederberger explains,

the reason relates to a statistical effect referred to as “regression to the mean.” Given any subjects with measurements related to a biological effect outside of the mean measurement for those subjects, such as a group of infertile men, they are *expected* to improve on subsequent testing simply because it is more likely that the next measurement will approach the mean. The only way to determine if such an improvement was due to chance or to a drug effect is to give a placebo to a separate group of subjects, and compare the outcomes of the placebo group to those of the group given the drug.

(Tab D ¶ 18.) (Emphasis in original.)

Defendants also rely on a more recent unpublished study by Martha Cuya partially funded by Lane Labs.<sup>12</sup> This study consisted of 47 infertile men and 12 men with normal sperm parameters who were given Maca and Maca-HAI. (Tab D ¶ 9.1.) As Dr. Niederberger notes, the authors of that study incorrectly suggest that the study was “double blind,”<sup>13</sup> because there was no placebo group, “a critical omission.” (Tab D ¶ 21.)

Moreover, none of the human studies addressing fertility detected “demonstrable changes in reproductive hormones coincident with *Lepidium meyenii* administration” (Tab D ¶ 21), making it unlikely that compounds based on this substance would improve fertility. (Tab D ¶ 21.) Thus, it is not reasonable, based on the limited and critically flawed studies submitted by the Defendants, to conclude that *Lepidium meyenii* will make a man more fertile. Indeed, the studies suggest that Defendants’ claims are probably untrue.

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<sup>12</sup> This study was not concluded until 2006 (Tab D ¶ 21), and thus, was not in the Defendants’ possession at the time they first began making claims that Fertil Male enhanced fertility. Under the Order against Lane Labs, it is necessary to have substantiation at the time the Defendants make a claim. (Tab A ¶ III.)

<sup>13</sup> Referring to this study as a “double-blind” study necessarily suggests the presence of a placebo group because it refers to a methodology in which investigators and subjects do not know who receives the placebo or the drug. (Tab D ¶ 18.)

Moreover, Dr. Niederberger explains that any competent and reliable scientific evidence that would substantiate the Defendants' claim that *Lepidium meyenii* – or Fertil Male – improves male fertility, would have to include:

- 1) animal studies that establish a plausible biological basis for improvements in male fertility (as distinguished from increased sexual activity);
- 2) human studies with a sufficient number of subjects that are designed and implemented in a manner that ensures that:
  - a) chance effects leading to observed improvements in fertility are excluded, traditionally by the inclusion of a placebo group separate from the treated group;
  - b) biases introduced by the investigators are excluded, traditionally by a double-blind design; and
  - c) clinically and statistically significant improvements are documented in outcomes that are relevant to an expected improvement in male fertility.

(Tab D ¶ 17.) The studies on which the Defendants rely to support their claims do not come close to meeting these basic requirements, and are thus not “competent and reliable scientific evidence” to support the Defendants' claims that Fertil Male increases a man's fertility. (Tab D ¶¶ 20-23.) The Defendants' further claim of

clinical support for this proposition is, therefore, demonstrably false as well. For these reasons, the Defendants' advertising of Fertil Male violates Paragraphs III and IV of the Order against Lane Labs and Andrew Lane. On this basis, the Defendants Lane Labs and Andrew Lane should be found in contempt for their advertising of this product.

**b. The Defendants Have Violated the Orders by Failing to Substantiate by Competent and Reliable Scientific Evidence Their Claims Regarding AdvaCAL, and by Misrepresenting the Results of Scientific Research**

As noted above, Paragraph III of the Orders requires that the Defendants have “competent and reliable scientific evidence” to substantiate representations about the effect of a product on the structure or function of the body or about any other health benefits of the product. (Tab A ¶ III.) Paragraph IV of the Orders bars the Defendants from misrepresenting “in any manner, expressly or by implication, ... the existence, contents, validity, results, conclusions, or interpretations of any test, study or research.” (Tab A ¶ IV.) The Defendants have violated both such provisions in their advertising of AdvaCAL.

To support their claims of superiority over other products, the Defendants rely on studies conducted by Dr. Takuo Fujita, the scientist who developed AdvaCAL. In 1999, Andrew Lane hired Dr. Robert Heaney of Creighton

University, a “world-recognized authority on calcium,” Metagenics, 1996 WL 615822 at \*19 (F.T.C. October 11, 1996), to evaluate Dr. Fujita’s research on AAACa (AdvaCAL). (Tab E ¶ 19 n.1.) At that time, Dr. Heaney informed the Defendants that they were relying on inadequate research to support their claim that AdvaCAL was superior to other forms of calcium. (Tab E ¶ 19 Exh. 3.) He suggested to Lane Labs that it conduct further independent testing on AAACa against another form of calcium to see which was more absorbable. (Tab E ¶ 19 Exh. 3.)

Thereafter, Lane Labs contracted with Creighton University to test the absorbability of AAACa (AdvaCAL) compared to Calcium Citrate (CitraCal). (Tab E ¶ 21a Exh. 8.) Far from finding AAACa superior, that study found Calcium Citrate to be more absorbable than AAACa. (Tab E ¶ 21a Exh. 8.) Notwithstanding these results, the Defendants proceeded to market AdvaCAL as superior to all other calcium products, including Calcium Citrate.

In connection with this contempt proceeding, Dr. Heaney again examined all of Dr. Fujita’s studies, along with the other materials the Defendants assert substantiate their claims, and concluded that this research does not constitute “competent and reliable” scientific support for the Defendants’ claims of AdvaCAL’s superiority. (Tab E ¶ 24.) The discussion below shows that there is

absolutely no support for Defendants' claims of superior absorbability, bone building, and fracture reduction.

**i. The Evidence Does Not Substantiate the Defendants' Claim that AdvaCAL is More Absorbable Than Other Types of Calcium**

The Defendants repeatedly claim that AdvaCAL is more absorbable than other calcium products. In fact, in numerous advertisements, Defendants claim that AdvaCAL is three times more absorbable than other calcium supplements. This claim is the predicate for all of the Defendants' claims of superiority in building bone and preventing fractures because, as Dr. Heaney explains in his declaration, once absorbed, all calcium loses its source identity. (Tab E ¶ 11.) "For the same amount of calcium absorbed, all calcium salts and supplements produce approximately the same effect." (Tab E ¶ 12.) Any superiority claim, therefore, rests upon proof of greater absorbability. As the discussion below details, neither the evidence relied upon by the Defendants, nor the body of scientific evidence on the subject of absorbability of calcium, supports the Defendants' claims that AdvaCAL is more absorbable than other calcium compounds. Therefore, not only must Lane Labs' claim of superior absorbability fail, but all of its other claims of superiority as well.

The Defendants' claim that AdvaCAL is "more absorbable" is unsubstantiated. First, the Defendants proffer no human studies to support their claims of superior absorbability.<sup>14</sup> There are human studies, however, that call into question the Defendants' claims. For instance, Dr. Heaney observed that data in the study reported in an article published by Dr. Fujita in 1996 in *Calcified Tissue International*, suggested that AdvaCAL was not absorbed at all. In that paper, Dr. Fujita et al. reported a fall in urinary calcium excretion in the group treated with AAACa. (Tab E ¶19 at 15.) Calcium absorption, however, is never associated with a fall in urine calcium. (Tab E. ¶ 19 at 15.) While Dr. Heaney rejects these implausible results as demonstrating a failure of study design (Tab E ¶ 19 at 15), he nevertheless observes that "the urine calcium, as reported, shows no evidence whatsoever of calcium absorption, and without calcium absorption, there can be no effect on bone mineral density." (Tab E ¶ 19 at 15.)

Furthermore, the Defendants' claim of superior absorbability is directly contradicted by the study commissioned by Lane Labs and conducted by Dr. Heaney before the Defendants began advertising and marketing AdvaCAL. In that

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<sup>14</sup> The animal studies they rely upon compare absorption of AACa to this product with HAI (Tab E ¶21a at 18), a seaweed derived compound ostensibly used to enhance the absorbability of AACa.

study, Dr. Heaney concluded that AdvaCAL is not as well absorbed as Citracal. (Tab E ¶ 21a at 19.)

The Defendants also repeatedly state that AdvaCAL is “three times more absorbable” than other calcium. (Tab C ¶ 21a at 18.) Dr. Heaney explains that scientifically this cannot be true. “[T]he calcium absorption fraction for most calcium sources (including milk) at a 300 mg load is approximately .30...” (Tab E ¶21a at 18.) “[F]or a source to be 3 times as absorbable as that, the fractional absorption would have to be .9 (or 90% of the ingested calcium absorbed). Except in low birth weight newborns with an immature gut, no calcium absorption fractions remotely close to .90 have ever been reported.” (Tab E ¶ 21a at 18.) Therefore, as a matter of scientific fact, the Defendants’ claim that AdvaCAL is three times more absorbable than other calcium is patently false. There is no substantiation for such a claim.

In summary, the existing evidence, including the evidence directly relied upon by the Defendants, does not support the Defendants’ claim that AdvaCAL is more absorbable than other types of calcium, and certainly not the much stronger claim that the product is “three times more absorbable.” This claim, as well as the Defendants’ other claims that are based on an assumption of greater absorbability,

are therefore unsubstantiated. On this basis, the Defendants should be held in contempt of the Order.

**ii. The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium or Prescription Products at Building Bone or Increasing Bone Mineral Density**

In addition to making unsubstantiated claims that AdvaCAL is more absorbable than other calcium products, Lane Labs claims that AdvaCAL is superior to other products at building bone or increasing bone mineral density. These claims, too, are not substantiated by the available evidence.

The Defendants do not explain what they mean by “build bone.” As Dr. Heaney explains, no calcium product is “a sufficient stimulus by itself to cause more bone to be formed,” (Tab E ¶ 21b at 20), although when taken with a bone active agent such as Eli Lilly’s Forteo, calcium may *help* to build bone. (Tab E ¶ 21b at 20.) In contrast to Forteo, which actually builds new bone, all that calcium can do is reclaim bone that has been undergoing remodeling (“that has been out of commission”). (Tab E ¶21b at 20-21.) This can result in a measurable increase in bone mineral density, although it does not literally indicate the introduction of new bone. (Tab E ¶ 21b at 21.) Even if one assumes, *arguendo*, that a discernible increase in bone mineral density brought about by the

reclamation of bone is tantamount to “building bone,” then AdvaCAL shares in the credit for that increase along with other calcium products. (Tab E ¶ 21b at 21.) The Defendants have not provided any evidence that would support their claim of superiority in this regard, however. (Tab E ¶ 21b at 21.)

According to Dr. Heaney, the studies relied upon by the Defendants to support their claims of superiority in increasing bone mineral density are defective in critical respects. One study by Dr. Fujita published in 1996 in *Calcified Tissue International* compared AAACa (AdvaCAL) to Calcium Carbonate and a placebo. (Tab E ¶ 19 at 13 Exh. 5.) That study consisted of elderly hospitalized women with a mean age of 80. (Tab E ¶ 19 at 13.) The data reported improvements for all three groups at 24 months. According to Dr. Heaney, this data must have been erroneous because “placebo-treated, 80-year-old women do not gain bone over a 24-month period.” (Tab E ¶ 19 at 13.) This anomaly is explained by a high drop-out rate and a defective study design. (Tab E ¶ 19 at 13-14.) The three groups began with 19, 17, and 20 persons, respectively, but at 24 months, had only 5, 6, and 7 remaining participants. (Tab E ¶ 19 at 13-14.) Dr. Heaney surmises, based on his experience, that the drop outs were the sickest and frailest individuals, and accordingly, the ones with the lowest starting bone mineral density values. (Tab E ¶ 19 at 14.) Every time such an individual dropped out of the study, the average

bone mineral density for the group increased. (Tab E ¶ 19 at 14.)<sup>15</sup> Dr. Heaney explains that, in any case, the study is unacceptable substantiation for the Defendants' claims of increased bone mineral density because the remaining sample size was "too small to permit any kind of useful conclusion." (Tab E ¶ 19 at 14.)

Dr. Heaney also explains that the analysis is scientifically invalid because it tracked group mean values rather than the within-individual changes. (Tab E ¶ 19 at 14.) In other words, rather than reporting the average change in bone mineral density for sets of particular individuals at each interval, Dr. Fujita reported the average bone mineral density for the groups as they were constituted at each interval.<sup>16</sup> (Tab E ¶ 19 at 15.) The results were distorted because the groups of individuals differed in their composition from one interval to the next.

Defendants also rely on another of Dr. Fujita's studies published in the *Journal of Bone and Mineral Metabolism* in 2000. That study found no significant change in lumbar spine density for any product, including AdvaCAL.

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<sup>15</sup> E.g., a group with values of 1, 2, 3, 4, 5, and 6 has an average of 3.5. If the individuals with values 1, 2, and 3 drop out, the average of the group, as it is then constituted, jumps to 5.

<sup>16</sup> See n. 15. What Dr. Fujita should have done is report, for each interval, the average changes in bone mineral density for the individuals who remained in the study for the duration.

(Tab E ¶ 19 at 17.) In addition, there was no statistically significant difference in the results for AdvaCAL and Calcium Carbonate in increasing radial bone mineral density. (Tab E ¶ 19 at 17.) The groups were not well matched in terms of age and baseline bone mineral density, and the sample sizes were too small (between 6 and 11 individuals per group). (Tab E ¶ 19 at 17.) As Dr. Heaney notes, “[t]his study ... produced an indeterminate result. Such studies should not be done, as they are clearly underpowered, and if done, should not be published.” (Tab E ¶ 19 at 17.)

The Defendants graphically depict their claims of superiority in increasing bone density on a chart seen in advertisements running from 2003 to 2006. (Tab C Exhs. 10 and 11.) One of the graphs in these advertisements purports to show two-year spinal bone density changes for both post-menopausal women and elderly women. (Tab C Exhs. 10 and 11.) Defendants depict AdvaCAL as increasing spinal bone density in post-menopausal women nearly 4 times better than Calcium Citrate Malate and nearly 3 times better than Calcium Citrate. (Tab C Exhs. 10 and 11.) For elderly women, the same chart shows that AdvaCAL increased spinal bone density nearly 4 times better than Calcium Carbonate and approximately 1.6 times better than Calcium Hydroxy Apatite. (Tab C Exhs. 10 and 11.) The graph depicting these comparisons also lists a series of studies that

purportedly support the representations made in that advertisement. (Tab C Exhs. 10 and 11.)

This chart deceptively conveys that head-to-head studies exist that directly compare AdvaCAL to the other products referenced. In fact, Defendants can point only to defective studies comparing AdvaCAL to Calcium Carbonate. (Tab E ¶ 19 at 13, 17.) AdvaCAL has not been directly compared with the other supplements in the chart and the data involving those supplements “come from very different studies involving very different populations and treatment conditions.” (Tab E ¶ 21c at 24.) Dr. Heaney also explains that “... the figures cited for such products are not representative of the totality of the evidence with the respect to the individual sources used in this comparison.” (Tab E ¶ 21c at 24.)

The data for Calcium Citrate Malate selectively displayed in the chart illustrates this point. Calcium Citrate Malate is “generally recognized to be the best absorbed calcium supplement in widespread market use, certainly at least as good as, if not better than, for example, calcium citrate or calcium carbonate.” (Tab E ¶ 19 at 11-12.) Given this, the comparative data displayed in the chart, showing a 1% increase in bone density for Calcium Citrate and a *decrease* of 1.2% for Calcium Citrate Malate over two years (Tab C Exhs. 10 and 11) is “paradoxical” (Tab E ¶ 19 at 12), and is not a result that would be seen in a side-

by-side study. As Dr. Heaney further explains, “[t]he results one gets from a given intervention depend heavily upon the underlying biology of the group concerned, and comparisons between products can be made only within such groups, not across groups that otherwise differ in important respects.”<sup>17</sup> (Tab E ¶ 19 at 12.) The chart central to Lane Labs’ advertising campaign for AdvaCAL misleads consumers into believing that the products described and the results depicted are from the same studies, not from several different ones. The Defendants’ presentation of data in this form is highly misleading and violates Paragraph IV of the Orders, which bars misrepresentations concerning the results of tests or studies.

The Defendants not only claim that AdvaCAL is superior to other calcium products; they also claim that AdvaCAL is equal or superior to certain prescription products used to treat osteoporosis (bone active pharmacologic agents). (Tab C Exh. 8.)<sup>18</sup> Dr. Heaney confirms that there is no evidence in the materials supplied by the Defendants nor is there any other research that supports this claim. (Tab E

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<sup>17</sup> Factors to consider in matching a group would include, but not be limited to, age, baseline bone mineral density, body weight, and fracture history.

<sup>18</sup> AdvaCAL’s price is several times higher than the price of other calcium products. As revealed in an email from Andrew Lane to a Middle Eastern distributor, this is because Lane Labs considers this product to be “on par” with prescription products. (Tab C Exh. 25.)

¶ 21b at 23.) To the contrary, “there is a scientific consensus that calcium, while useful and necessary, is not as potent in reducing fracture risk as the bone active pharmacologic agents taken with calcium.” (Tab E ¶ 21b at 23-24.) In any case, there are no studies comparing AdvaCAL to prescription drugs such as Evista and Fosomax. Lane Labs’ claim that AdvaCAL is comparable or superior to these drugs therefore lacks substantiation.

Furthermore, Defendants’ claims that AdvaCAL is comparable or superior to prescription products may encourage at-risk consumers to take AdvaCAL in lieu of such prescription products, and are, therefore, affirmatively dangerous. Consumers who substitute AdvaCAL for prescription drugs based on the Defendants’ advertising may increase their risk of fracture and related health problems associated with the loss or weakening of bone.

In summary, none of the Defendants’ claims of AdvaCAL’s superiority to other calcium or to prescription products in “building bone” or increasing bone mineral density is substantiated. By claiming superiority, the Defendants give the misleading impression that AdvaCAL has actually been tested against prescription products and against calcium products other than Calcium Carbonate. The Defendants post what is ostensibly comparative data against data for AdvaCAL when the “comparative” data is actually derived from studies with different

subjects and conditions. No valid comparison between and among these products can be made based on these studies. Moreover, the studies the Defendants rely on to justify their claim of AdvaCAL's superiority in building bone mineral density are critically flawed and unreliable. The Defendants have, accordingly, violated Paragraphs III and IV of the Order and should be held in contempt.

**iii. The Evidence Does Not Support the Defendants' Claims that AdvaCAL is Superior to Other Calcium Products in Avoiding or Reducing the Risk of Fractures**

In addition to claiming that AdvaCAL is more absorbable than other calcium brands, and more effective at building bone density, Lane Labs claims that by taking AdvaCAL, one will avoid fractures. This claim is captured in a sweeping statement in an AdvaCAL infomercial, "you don't have to be in a nursing home because you broke your hip – all you have to do is take your AdvaCAL to prevent that." (Tab C Exh. 11.) The Defendants also make the fracture reduction claim in advertisements comparing AdvaCAL to other products. For instance, in the chart featured so prominently in AdvaCAL advertisements (Tab C Exhs. 10 and 11), the Defendants claim that over a 36-month period, AdvaCAL reduces fractures among elderly patients 100%. This advertisement compares AdvaCAL's supposed fracture reduction rate to those of Calcium Citrate Malate, Calcium Carbonate and

Calcium Hydroxy Apatite. (Tab C Exhs. 10 and 11.) In another advertisement with the heading “World-Famous AdvaCAL™ researcher reports ... AdvaCAL™ Users Have Fewer Fractures!,” Dr. Fujita is reported to say that “AdvaCAL users had a nearly unbelievable rate of 0 fractures per thousand patient years. This contrasts to 357 fractures per thousand patient years for calcium carbonate and more than 500 fractures per thousand patient years for those who took a placebo.” (Tab C ¶ Exh. 14.)

Dr. Heaney explains that the Defendants’ claims of fracture avoidance – whether stated generally or in comparison to other products – are not supported by the research relied upon by the Defendants nor are they supported by the larger body of scientific research on calcium dealing with fracture reduction.

No bone active agent, nutritional or pharmaceutical, can prevent all fractures (the usual meaning of avoid). Adequate calcium intake, particularly when coupled with normal vitamin D status, has been reported in well-controlled studies to reduce fractures in various studies and at various skeletal sites by 30 to 55%. Similarly, various pharmacologic agents have been shown to reduce fracture risk by roughly 40 to 70%. Nothing reduces fractures by 100%.

(Tab E ¶ 21c at 25.)

Dr. Fujita authored one paper dealing with AdvaCAL’s effects on fractures. That paper, published in 2004 in the *Journal of Bone and Mineral Metabolism*, was a reappraisal of the study published in *Calcified Tissue International* in 1996

referred to above, *supra* at 23. (Tab E Exh. 5.) Both the claim of “100% fracture reduction” and a “rate of 0 fractures per thousand patient years” are purportedly derived from that underlying study, which is wholly inadequate support for those claims. Dr. Heaney points out that

the fracture figures cited in that study are impossible to interpret since they are expressed as numbers of fractures per 1,000 subject years, without providing the number of subject years actually experienced; moreover the absolute number of fractures is, itself, not even mentioned. Since the study duration was 2.5 years, and by the end of the study, three-fourths of the subjects had dropped out, it can be roughly estimated that there were perhaps no more than 10 actual person years of observation in each group. While the paper records no fractures in the AAACa-treated group, a finding of 0 out of 10 is actually consistent with a true fracture rate of anywhere from 0% to as high as 31%. The confidence intervals for the estimated fracture rates for the three groups are not given, and should have been.

(Tab E ¶ 19 at 15-16.)

The strongest evidence that these claims are unsubstantiated, however, comes from Dr. Fujita himself. In a 1999 interview, he observed that the study published in 1996 in *Calcified Tissue International* was inconclusive as to the effect of AdvaCAL on fractures:

Of course, any increase in [bone mineral density] promises fewer fractures and for women in their eighties, there was no increase in fractures while they were on AAACa, but out of the thirty-placebo-controlled subjects there were three fractures. This number is not large enough but it suggests that AdvaCAL prevents decrease in bone strength. So it's quite possible that AdvaCAL would prevent fractures.

(Tab E ¶ 7.) Thus, the Defendants’ claims of superior fracture avoidance are based on improper extrapolation, a faulty analysis, and inconclusive results. The Defendants therefore lacked adequate substantiation for such claims and misrepresented the results of the tests from which they were derived.<sup>19</sup>

**B. William Lane is in Contempt of the Order Against Him Because he Made Unsubstantiated Representations as an Expert Endorser for AdvaCAL**

In several of Defendant Lane Labs’ advertisements, including infomercials, print advertisements, and catalogs, Dr. William Lane touts the health benefits of AdvaCAL. These advertisements present him as a knowledgeable “doctor” with expertise on calcium. In this advertising, he makes a number of statements regarding AdvaCAL that are unsubstantiated or misrepresent testing of AdvaCAL and other calcium products in violation of Parts III and IV of the Order against him. For example, his infomercial statements include the following:

“It’s the only calcium I’ve seen that has been shown over and over to build bone density.”(Tab C Exh. 10.)

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<sup>19</sup> The Defendants’ claim of fracture avoidance, as displayed graphically in Tab C Exhs. 10 and 11, also misrepresents studies and research because the evidence cited in the chart comparing AdvaCAL’s fracture reduction rate with those of Calcium Citrate Malate, Calcium Carbonate, and Calcium Hydroxy Apatite “come from very different studies involving very different populations and treatment conditions.” (Tab E ¶ 21c at 24.)

“Only calcium I know of that can increase bone density.” (Tab C Exh. 13 at 10.)

AdvaCal ends up “highly available, highly absorbable – in fact, 3-times as available as this [other form of] calcium.” (Tab C Exh. 13 at 24.)

“Most of the supplements out there don’t have available, digestible calcium.” (Tab C Exh. 13 at 37.)

Regular calcium is so hard that the body “cannot absorb it – like a rock!” It “goes in one end and out the other.” (Tab C Exh. 13 at 24.)

In a print advertisement, Dr. Lane, who is pictured, states, “AdvaCAL™ is the #1 Bone Building Calcium. Period.” (Tab C Exh. 10.) That same advertisement features the graphs referred to in Section III.A.2.b.ii, above (Tab C Exhs. 10 and 11), that purport to summarize data from studies referenced in the advertisement.

Finally, Dr. Lane was pictured in numerous “stories” about AdvaCAL that appeared in CompassioNet catalogs under the heading “AdvaCAL™ is a TV Star!” In the article Dr. Lane is quoted as saying that calcium carbonate is “cheap” but “nearly impossible for our bodies to absorb” and that “as much as 80% of the calcium passes through without doing our bodies any good.” (Tab C Exh. 13.) In other versions of “AdvaCAL™ is a TV Star!” he is quoted as saying that AdvaCAL is “highly absorbable” compared to other calcium products. (Tab C

Exh. 13.)

William Lane's claims of AdvaCAL's superiority are not adequately substantiated, and misrepresent the results of tests and studies on AdvaCAL and other calcium products. Therefore, William Lane, along with Defendants Lane Labs and Andrew Lane, should be held in contempt of the Order against him.

**C. Consumers Must be Compensated for the Defendants' Contumacious Behavior<sup>20</sup>**

Lane Labs claims that Fertil Male enhances a man's fertility, but there is no competent and reliable scientific evidence to support this proposition. Indeed, the evidence suggests that Lane Labs' claims regarding Fertil Male are probably false. Notwithstanding these facts, Lane Labs marketed and sold Fertil Male to thousands of people.

Lane Labs similarly marketed and sold AdvaCAL without any substantiation for its claims of superiority over other calcium products and comparability or superiority to prescription products used to treat osteoporosis. Based on these extraordinary, unsupported, and false claims of superiority, Defendants successfully charged a significant premium for AdvaCAL.

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<sup>20</sup> A more complete discussion of damages is contained in a second brief being filed under seal.

The Defendants' sales – on the order of millions of dollars – translate into real losses by consumers – losses for which consumers are entitled to be compensated. Accordingly, the FTC asks that this Court, after hearing of the matter and assessing the evidence of damages arising from the Defendants' order violations, exercise its discretion and award full compensation to the victims of the Defendants' wrongful and contumacious advertising.

#### **IV. Conclusion**

For all of the foregoing reasons, the FTC asks that this Court issue an order, requiring Defendants to show cause why they should not be held in contempt.

Dated: January 12, 2007

WILLIAM BLUMENTHAL

General Counsel

/s Elsie B. Kappler

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